K041172

NOV 18 2004

APPENDIX A

510(k) PREMARKET NOTIFICATION SUMMARY

(Per 21 CFR 807.92)

I. Applicant:

Teresa Yang
Basba Inc.
15342-B East Valley Blvd.
City of Industry CA 91746
626 / 336-9737 telephone
626 / 336-9237 facsimile
Email: TY1688@yahoo.com

Key Contact:

M. Joyce Heinrich
Texas Applied Biomedical Services, Inc.
12101 Cullen Blvd., # A
Houston, Texas 77047
713 / 734-4433 telephone
713 / 734-5671 facsimile
Email: tabsii@msn.com

II. Device Name

Proprietary Name:	Basba E-Machine
Common / Usual Name:	TENS Device
Classification Name:	Transcutaneous electrical nerve stimulator
Product Code:	GZJ

III. Predicate Device

The Basba E-Machine is substantially equivalent to other Transcutaneous Electrical Nerve Stimulator (TENS) devices currently in commercial distribution such as the Apex Medical Corporation's Apex Medical Digital TENS TS1211, TS1212 (K021755) and Biomedical Life Systems, Inc. Electro-Nerve Stimulator TENS, Model Bmls03-5 (K033455).

IV. Intended Use of the Device

The Basba E-Machine is intended for use as a symptomatic relief and management of chronic and acute pain and as an adjunctive treatment in the management of post-surgical and post-traumatic pain.

V. Description of the Device

The Basba E-Machine is a non-invasive, transcutaneous electrical stimulation device, which is intended for use as an adjunctive treatment for individuals suffering from chronic intractable pain. The system consists of a TENS Unit, AC-DC adapter to power the unit and a serial RS-232 connection cable. The Unit is approximately 17 cm x 15 cm x 4 cm. Two light emitting diodes (LED) are located on the faceplate of the Unit. The green LED indicates the working status of the device and the red LED is the power indicator. There are four sockets located on the faceplate of the Unit: three of them labeled "OUT" provide the output electrical current for 3 different types of connectors and the fourth socket is the ground socket labeled GND.

VI. Summary of the Technical Characteristics of the Basba E-Machine as Related to the Referenced Predicate Devices.

The Basba E-Machine has comparable technical and performance characteristics as currently marketed TENS devices. The E-Machine and the referenced predicate devices use similar electronic components to provide electrical stimulation via paired electrodes to the subject. All of these devices are operated at continuous wave duty cycles.

VII. Testing

Testing of the Basba E-Machine includes functional performance testing and electrical safety testing.

VIII. Conclusions

In comparison to the predicate devices, the Basba E-Machine has the same intended uses and similar technical, functional and performance characteristics. The Basba E-Machine is designed to comply with the generally accepted performance specifications for TENS devices.

The Basba E-Machine performs as intended and does not raise any new safety or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2004

Basba Inc.
C/o Mrs. M. Joyce Heinrich
Texas Applied Biomedical Services, Inc.
12101 Cullen Boulevard, #A
Houston, Texas 77047

Re: K041172
Trade/Device Name: Basba E-Machine
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: November 9, 2004
Received: November 15, 2004

Dear Mrs. M. Joyce Heinrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

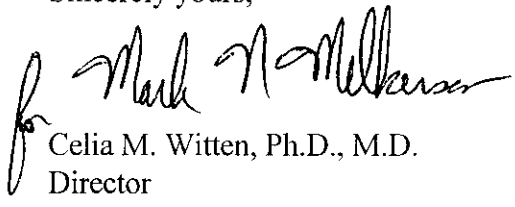
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX B

Indications for Use

510(k) Number (if known): Pending K041172

Device Name: **Basba E-Machine**

Indications for Use:

The Basba E-Machine is intended for temporary symptomatic relief and management of chronic intractable pain and as an adjunctive treatment in the management of post-surgical and post-traumatic pain.

Prescription Use: X **AND/OR** **Over the Counter Use:** ____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODpE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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